

**CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE**

**INITIAL STATEMENT OF REASONS FOR THE  
PROPOSED ADOPTION OF THE CIRM GRANT ADMINISTRATION POLICY FOR  
FOR-PROFIT ORGANIZATIONS**

**HEARING DATE:** None Scheduled.

**SUBJECT MATTER OF PROPOSED REGULATIONS:** CIRM Grant Administration Policy  
for For-Profit Organizations

**SECTIONS AFFECTED:** The proposed regulations adopt Chapter 5 and section 100501 of  
Title 17 of the California Code of Regulations.

**SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH ADOPTION:**

**SECTION 100700 – GRANTS ADMINISTRATION POLICY:**

**Purpose:**

The purpose of Section 100700 is to describe the terms and conditions by which  
recipients of facilities and equipment grants must abide during the term of the grant.

**Subdivision (a):** This subdivision describes the scope of the regulation, indicating the  
regulation reaches recipients of a facilities grant as authorized by Health and Safety Code  
section 125290.70 from the CIRM. The subdivision incorporates by reference the  
CIRM's Grant Administration Policy for For-Profit Organizations as identified  
specifically in subdivision (b) of the regulation.

**Subdivision (b):** This subdivision identifies which provisions of the policy are being  
incorporated by reference. The policy in its entirety is to be incorporated, with the  
exception of its preface.

**Subdivision (c):** This subdivision indicates when amendments to the policy (effectuated  
by amendment to this regulation) are effective as to grants already funded and active. In  
such circumstances, the new policy terms will become effective on the anniversary date  
of the Notice of Grant Award following the effective date of the regulation's amendment,  
unless specified otherwise in the regulation or policy amendment.

**Subdivision (d):** This subdivision indicates the term of enforcement of the policy and  
informs grantees that should the CIRM cease to exist the provisions of the regulation  
remain enforceable by the State of California.

Rationale:

**Subdivision (a)** is necessary to provide clarity in the scope of the policy – applicable to recipients of facilities and equipment grants. The subdivision establishes the rule that all covered recipients are bound by the terms and conditions of the policy.

Title 1 of the California Code of Regulations, section 20, permits agencies to incorporate by reference documents under certain conditions. Subdivision (c)(1) of that regulation allows such incorporation when to do otherwise be “cumbersome, unduly expensive, or otherwise impractical” to publish the document in regulatory form. In light of the size and magnitude of the policy and given the burdens associated with translating each of the document’s separate provisions into specific regulations, incorporation by reference serves the needs of both efficient use of resources, avoids the cumbersome task of rewriting an entire manual, and avoids the risk of inadvertent disagreement between the regulations and the policies being implemented.

**Subdivision (b):** This section clarifies the specific sections of the policy which are being incorporated by reference, as permitted by Title 1 of the California Code of Regulations, section 20, subdivision (c)(5). Because the unincorporated part of the policy is informational or background material only, it is not incorporated in the regulation.

**Subdivision (c):** This subdivision is necessary to address what will be a common-place circumstance, wherein active grants that may span several years will become subject from time to time to amendments to the policy. Once those amendments are effective (through amendment of the policy and the regulation incorporating it), the regulation clarifies that the amended policy will become effective as to existing grants at the anniversary date of the Notice of Grant Award.

**Subdivision (d):** The rationale for this subdivision is to ensure that grantees are aware that the terms and conditions of the grant awards survive even in the event the CIRM should no longer exist.

**DOCUMENT INCORPORATED BY REFERENCE:**

**CIRM GRANT ADMINISTRATION POLICY FOR FOR-PROFIT ORGANIZATIONS**

**CHAPTER IX –GRANTS ADMINISTRATION POLICY for FOR-PROFIT ORGANIZATIONS:**

**Subpart B. Incorporation by Reference**

Purpose: This subpart states that CIRM's Grants Administration Policy for Academic and Non-Profit Institutions and any appendices are incorporated by reference, except as to those sections identified in Subpart C. The subpart also states that this policy applies to for-profit organizations funded through grants.

Rationale: Many portions of the non-profit GAP are important and necessary components regardless of whether the grantee is a for-profit or non-profit organization. After much discussion and research, it was concluded that only small number of the non-profit GAP's provisions needed to be tailored for the for-profit grantee. As a result, it was deemed most efficient to incorporate the existing non-profit GAP into the for-profit GAP and identify the areas where different provisions would apply in the for-profit context

**Subpart C. Provisions of the Non-Profit GAP Modified for this Policy**

Purpose: This subpart identifies the specific areas of the non-profit GAP that are amended for the for-profit GAP. Each heading that follows is the counterpart in the non-profit GAP, as codified in Title 17, California code of Regulations, section 100500.

**SECTION II. GRANT APPLICATION AND REVIEW PROCESS.**

**Subpart A.1. PI and PD Eligibility:**

Purpose:

The subpart describes the educational requirements for service as a PI or PD. This section also states the a PI or PD must be employed primarily (over 50% time) by the for-profit organization at the time of award and during the entire project period.

Rationale:

This subdivision is necessary to meet statutory requirements of the CIRM that it fund research in California and that is support California researchers. Moreover, CIRM believes the employment minimum of 50% helps to ensure that the PI or PD identified in the grant application will in fact be able to support and oversee the funded research.

**SECTION III. PRE-AWARD AND AWARD.**

**Subpart C. Public Policy Requirements.**

**9. Sharing of Publication-Related Biomedical Materials**

Purpose: This subpart identifies public policies governing certain activities upon which CIRM funding is contingent. This subsection states that grantees shall share biomedical

materials first created with CIRM funding and described in published scientific articles for research purposes in California as specified in CIRM's intellectual property policy for for-profit organizations – specifically, Title 17, California Code of Regulations, section 100404. The section also states that annual reporting requirements pertinent to inventions and discoveries are governed by section 100402 of that policy.

Rationale: This section is necessary to alert grantees of their sharing and reporting obligations contained in other CIRM policies and regulations.

## SECTION V. PAYMENT AND USE OF FUNDS.

### **B. Costs and Activities**

Purpose: The purpose of this section is to describe the procedures that will guide how and when payments of grants will be made and the rules applicable in the expenditure by grantees of those funds. CIRM funds shall only be used for expenditures necessary to carry out the approved project and activities. The section identifies specific allowable and unallowable costs that can be charged by grantees to the grant funds.

Rationale: Cost allocation formulae are necessary to ensure grantees and the public are aware of costs that are allowable and that can be assessed against the grant funds, ensuring proper expenditure of taxpayer-funded research.

### **D. Prior Approval Requirements**

#### **5. Award Transfer**

Purpose: This section describes the circumstances under which a CIRM grantee must seek prior approval from CIRM for award transfer. With prior approval, the continuation of CIRM grant activities may be transferred to another eligible California organization in the events described. The section also describes the administrative process for seeking prior approval from CIRM for such a transfer.

Rationale: Prior approval requirements, which are similar to those of the NIH, AHA, SRP and JDRF, ensure that flexibility in the research process is balanced with proper oversight.

### **H. Reporting Requirements**

#### **3. Other Reports**

Purpose: Subpart H details the financial and programmatic reporting requirements. Section 3 states that grantees are obliged to file reports of invention, patent and licensing activities pursuant to Title 17, California Code of Regulations, section 100402.

Rationale: This section is necessary to ensure grantees are aware of reporting requirements contained not only in the GAP but also elsewhere in CIRM policies, such as the intellectual property policy.

## **I. Grant Close-Out**

Purpose: This section addresses the procedures and expectations for close-out of a grant after the project period end date. Grantees remain obligated to return funds due as a result of refunds, corrections or other transactions. Close-out of a grant does not cancel any requirements for property accountability, record retention, reporting or financial accountability. Following close-out, the grantee remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and CIRM may recover amounts based on the results of an audit covering any part of the period of grant support. In addition, the grantee is obligated to report to CIRM after grant close-out any patents filed, patents issued, licenses granted, or revenue received that resulted from CIRM-funded research (see Title 17, California Code of Regulations, sections 100400 *et seq.*).

Rationale: Grant close-out procedures are necessary to ensure grantees are aware of their obligations when a grant concludes, and ensures the CIRM is able to fulfill its obligations to ensure proper accounting of CIRM funds.

## **K. Written Notification Requirements**

Purpose: This section identifies circumstances requiring a grantee to provide written notification to CIRM within 30 days: 1) Change in organizational status, including but not limited to a corporate acquisition, consolidation, dissolution or merger. In the case where intellectual property exists as a result of CIRM-funded programs, any acquiring organization shall assume responsibility for all provisions of the CIRM Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations (see Title 17, California Code of Regulations, sections 100400 *et seq.*); 2. Licensing activity related to CIRM-funded research; 3) Termination of a program that is currently funded by CIRM. The grantee organization will be required to submit a final report on the project and a final financial report within 90 days of the effective date of award termination. All unexpended funds as of 30 days of the date of award termination must be returned to CIRM within 60 days of termination of the award. Further, the grantee organization shall continue to be responsible for all ongoing obligations of the award under the CIRM Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations (see Title 17, California Code of Regulations, sections 100400 *et seq.*).

Rationale: This section is necessary to ensure grantees are aware of their obligation to provide written notice of certain events as contained in the CIRM's intellectual property policy. In addition, these reporting requirements and events ensure CIRM is aware of significant events that may trigger other obligations or may have a significant impact on the research to be funded. This ensures CIRM is able to fulfill its proper oversight role.

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